

NEWSLETTER

dari UPM



EDISI 11

2 Mei 2012

UNIT PENJAMINAN MUTU



COMMON FINDINGS IN ISO 9001:2008 AUDITS



Dalam kegiatan audit Sistem Manajemen Mutu berdasarkan ISO 9001:2008 seringkali ditemukan temuan-temuan (*findings*) seperti yang akan dijabarkan di bawah ini. Temuan-temuan tersebut dapat berbeda kadar atau berat ringannya, sehingga untuk menentukan langkah perbaikan (tindakan koreksi) akan sangat tergantung pada akar masalahnya (*root cause*) yang mungkin akan berbeda-beda dari satu organisasi ke organisasi yang lainnya. Banyak cara untuk menentukan akar masalah (*root cause analysis*), di antaranya adalah dengan metode 3-Why; 5-why; *fishbone analysis* (Ishikawa diagram), dan sebagainya.

Temuan-temuan yang seringkali didapati selama proses audit (*common findings*) adalah sebagai berikut :

Klausul 4.1 Persyaratan Umum (General Requirements)

- Proses yang di-outsource tidak dijelaskan secara memadai dalam dokumentasi SMM.
- Urutan dan interaksi antar proses yang ada di organisasi tidak dijelaskan secara memadai dalam dokumentasi SMM.

Klausul 4.2 Persyaratan Dokumentasi (Documentation Requirements)

- Organisasi hanya membuat dokumentasi wajib (kebijakan Mutu, Manual/ Panduan mutu dan 5 prosedur wajib) tetapi 'lupa' membuat dokumen yang diperlukan oleh organisasi untuk menjamin efektifitas perencanaan, pengoperasian dan pengendalian proses-prosesnya.
- Organisasi tidak menyatakan secara spesifik ruang lingkup (*scope*) dari SMMnya.
- Organisasi mengecualikan (*exclude*) suatu

proses (contohnya design di industri kosmetik atau farmasi) hanya karena 'enggan' R&Dnya diaudit atau 'khawatir' rahasia formulasinya diketahui pihak luar meski jelas-jelas aktivitas itu ada dan penting untuk keberlangsungan organisasi, padahal auditor di Lembaga Sertifikasi



nya masing-masing terikat dengan 'confidentiality agreement'

Klausul 4.2.3 Pengendalian Dokumen (Control of documents)

- Prosedur Pengendalian dokumen tidak memadai pengendalian dokumen dalam bentuk soft copy dan atau dokumen yang berasal dari pihak eksternal yang penting untuk keberlangsungan SMM.
- Dokumen yang kadaluarsa tidak ditarik oleh DC (*Document Controller*) atau tidak ditandai secara memadai untuk mencegah penggunaan yang tidak disengaja (*unintended use*)
- Terdapat revisi 'tak resmi' (*unauthorized amendment*) dalam dokumen yang beredar
- Dokumen yang sudah direvisi tidak segera diedarkan, sehingga dokumen yang di master DC berbeda dengan yang beredar di lapangan
- Dokumen tidak di-approve (atau di-reapprove jika revisi) oleh personnel yang berwenang

Klausul 4.2.4 Pengendalian Rekaman (Control of Records)

- Masa simpan (*retention time*) tidak ditentukan atau ditentukan tanpa memperhitungkan kepentingan legal atau kepentingan customer (e.g. di industri pangan, masa simpan yang terkait dengan *batch records* seharusnya disimpan hingga 6 bulan sesudah *expiry date*).
- Data atau rekaman yang berasal dari pihak external tetapi perlu untuk efektifitas SMM tidak ditentukan masa simpannya (e.g. sertifikat training; sertifikat kalibrasi; CoA)
- Masa simpan untuk data/rekaman dalam bentuk *soft copy* tidak ditentukan masa simpannya (note: boleh berbeda dengan yang *hard copy*)
- Data/rekaman tidak di-approve oleh personnel yang berwenang

"Quality means doing it right when no one is looking"

HENRY FORD

"Masa depan itu dibeli oleh masa sekarang"

SAMUEL JOHNSON

TIM :

PENGARAH

LINDA PURNAMASARI

KOORD.

BAGUS SUMINAR

TIM REDAKSI

MAHMUDDA N. Z

EVA NURJANNAH

NIKE AMANDA

Usulan & Saran Bapak/Ibu/Saudara sangat kami harapkan. Silahkan hubungi Tim Redaksi di Ruang UPM No ext .113

HIMBAUAN :

Simpanlah newsletter ini untuk referensi di masa datang

To be continue.....(1 dari 10)

NEWSLETTER

dari UPM

Inside Story Headline



Caption describing picture or graphic.

This story can fit 150-200 words.

One benefit of using your newsletter as a promotional tool is that you can reuse content from other marketing materials, such as press releases, market studies, and reports.

While your main goal of distributing a newsletter might be to sell your product or service, the key to a successful newsletter is making it useful to your readers.

A great way to add useful content to your newsletter is to develop and write your own articles, or include a calendar of upcoming events or a special offer that promotes a new product.

You can also research articles or find "filler" articles by accessing the World Wide Web. You can write about a variety of topics but try to keep your articles short.

Much of the content you put in your newsletter can also

be used for your Web site. Microsoft Publisher offers a simple way to convert your newsletter to a Web publication. So, when you're finished writing your newsletter, convert it to a Web site and post it.

"TO CATCH THE
READER'S
ATTENTION,
PLACE AN
INTERESTING
SENTENCE OR
QUOTE FROM
THE STORY
HERE."

Inside Story Headline

This story can fit 100-150 words.

The subject matter that appears in newsletters is virtually endless. You can include stories that focus on current technologies or innovations in your field.

You may also want to note business or economic trends, or make predictions for your customers or clients.

If the newsletter is distributed internally, you might comment upon new procedures or improvements to the business. Sales figures or earnings will show how your business is growing.

Some newsletters include a column that is updated every issue, for instance, an advice column, a book review, a letter from the president, or an editorial. You

can also profile new employees or top customers or vendors.

Inside Story Headline



Caption describing picture or graphic.

This story can fit 75-125 words.

Selecting pictures or graphics is an important part of adding content to your newsletter.

Think about your article and ask yourself if the picture supports or enhances the message you're trying to convey. Avoid selecting im-

ages that appear to be out of context.

Microsoft Publisher includes thousands of clip art images from which you can choose and import into your newsletter. There are also several tools you can use to draw shapes and symbols.

Once you have chosen an image, place it close to the

article. Be sure to place the caption of the image near the image.

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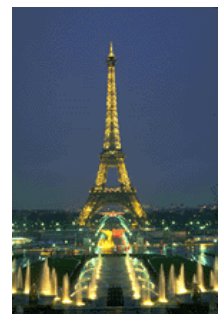
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Caption describing picture or graphic.

Your business tag line here.

UNIT PENJAMINAN MUTU

Primary Business Address
Your Address Line 2
Your Address Line 3
Your Address Line 4

Phone: 555-555-5555
Fax: 555-555-5555
E-mail:
someone@example.com

This would be a good place to insert a short paragraph about your organization. It might include the purpose of the organization, its mission, founding date, and a brief history. You could also include a brief list of the types of products, services, or programs your organization offers, the geographic area covered (for example, western U.S. or European markets), and a profile of the types of customers or members served.

It would also be useful to include a contact name for readers who want more information about the organization.

**We're on the
Web!
example.com**

Back Page Story Headline

This story can fit 175-225 words.

If your newsletter is folded and mailed, this story will appear on the back. So, it's a good idea to make it easy to read at a glance.

A question and answer session is a good way to quickly capture the attention of readers. You can either compile questions that you've received since the last edition or you can summarize some generic questions that are frequently asked about your organization.

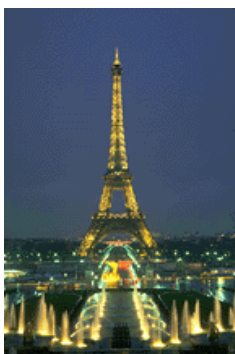
A listing of names and titles of managers in your organization is a good way to

give your newsletter a personal touch. If your organization is small, you may want to list the names of all employees.

If you have any prices of standard products or services, you can include a listing of those here. You may want to refer your readers to any other forms of communication that you've created for your organization.

You can also use this space to remind readers to mark their calendars for a regular event, such as a breakfast meeting for vendors every third Tuesday of the month, or a biannual charity auction.

If space is available, this is a good place to insert a clip art image or some other graphic.



Caption describing picture or graphic.